CRITERION 3 – QUALITY IMPROVEMENT

Concerns:

- The term *nonconformities* is used without being clearly defined in the *Corrective and Preventative Action Procedure*. Also, the procedure uses general terms such as *complex*, *simple,* and *high risk* without clearly defining them.
- The criteria for determining the need for a *simple* versus *complex* root cause analysis, contained in the Appendix of the Fermilab *Corrective and Preventive Action Procedure,* lacks sufficient direction for consistent application. (It is noted that the *Root Cause Procedure* is still in development.)

CRITERION 5 – WORK PROCESSES

Concern:

- There appears to be some confusion regarding the roles and responsibilities related to the maintenance of the official WSS set, as evidenced by the processing of the 2008 version of the Fermilab WSS set.

CRITERION 6 – DESIGN

Concerns:

- Design processes in the laboratory are not consistent. In some areas of Fermilab design work at Fermilab is dependent on the experience of the staff and management/engineer interactions while in others, such as FESS, the process is well defined.
- The decision to create and staff the position of Chief Engineer has not been finalized.

CRITERION 6 – DESIGN, CONTINUED

Significant Concern:

- The draft Fermilab *Engineering Manual*, revision 0.2, does not provide sufficient detail and rigor to effectively implement the requirements of Criterion 6 *Design* and Criterion 5.a *Work Processes* of DOE O 414.1C *Quality Assurance*, and Chapter Six *Design* and Section 5.3 *Work Process Control* of the Fermilab *Integrated Quality Assurance* program, or to adequately address the inadequacies identified in the Fermilab *Root Cause Analysis for the Large Hadron Collider Magnet System* report. The Fermilab *Engineering Manual* must appropriately balance, and therefore benefit from the strengths of, the Laboratory's strong scientific and engineering expertise, and a more formal process-based approach to the engineering design process.

CRITERION 8 – INSPECTION AND ACCEPTANCE TESTING

Concern:

- The level of documentation of acceptance testing varies between the various Fermilab D/S/Cs.

CRITERION 9 – MANAGEMENT ASSESSMENT

Concerns:

- The draft *Fermilab Management Assessment Procedure* does not require identification of the assessment criteria, or provide direction/guidance on how to scope assessments. This is important direction to provide to line organizations to ensure assessment are not too broadly scoped for the available resources to adequately cover the topic in a reasonable time and with sufficient depth and rigor to add value.

CRITERION 9 – MANAGEMENT ASSESSMENT, CONTINUED

- Some terms such as *minor findings, significant findings, special assessments, Fermilab Director's Assessments,* and *third party assessments* are not sufficiently defined to allow for consistent application. In addition, some terms in the *Definitions* Section that are useful for characterizing the significance of assessment issues are not used in the body of the document or in other documents germane to assessments (i.e., IQA, FICAP, draft *Management Assessment Procedure* and *Corrective & Preventive Action Procedures*).

SUSPECT/COUNTERFEIT ITEMS PREVENTION

Concerns:

- Some line organizations were not sure what role OQBP played in S/CI. They believe OQBP owns the Laboratory's process, but were not sure what exactly that means in terms of dealing with S/CI when found. The Laboratory's S/CI program document is still in draft, which may contribute to this perception.
- TD, PPD, and AD each have a collection of S/CI in their facilities that they have identified and have segregated out of the workflow. The perception is they are holding these items until the Laboratory-wide S/CI program is "up and running", pending the release of the draft OQBP S/CI Procedure. Having these S/CI out in the field poses a vulnerability.

SUSPECT/COUNTERFEIT ITEMS PREVENTION, CONTINUED

Corrective Action Requirements:

- Fermilab must provide FSO with their proposed resolution for each of the concerns identified in this assessment report. Fermilab must provide a Corrective Action Plan for the significant concern identified by this assessment, for approval by FSO. Prior to the resolutions and corrective action plan being finalized and signed-off by the Fermilab Director, FSO will meet with the Laboratory to review and discuss the proposed actions. The Laboratory's response is due to FSO within thirty (30) days of the issuance of the final assessment report.